

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS

Washington, D.C. 20231

| Α | PPLICATION NO. | FILING DATE | | FIRST NAMED INVENTOR | | ATTOF | RNEY DOCKET NO. |
|---|-----------------------|----------------------------|------------------------|----------------------|-----------|----------|-----------------|
| | 09/535, | 951 03/2 | 7/00 | SCHREIBER | | Ą | 555-56 |
| _ | | | | HM12/0619 7 | | EXAMINER | |
| | | VANDERHYE | | | | HUI,S | |
| | ARL INGT | RTH GLEBE I DN VA 2220: | 1 4 7 4 4 1 4 7 4 4 | FLUOR | ART UN | NIT | PAPER NUMBER |
| | FILVION de PAPEAL ; V | 204 VPI ZZZU. | 4/14 | | DATE MAIL | 1617 | 4 |
| | | | | | DAIE MAIL | .EV: | 06/19/01 |

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

| | I Americani al | | | | | | | |
|--|--|--------------------|--|--|--|--|--|--|
| • | Application No. | Applicant(s) | | | | | | |
| Office Action Summary | 09/535,951 | SCHREIBER, ALAN D. | | | | | | |
| · | Examiner | Art Unit | | | | | | |
| | San-ming Hui | 1617 | | | | | | |
| The MAILING DATE of this communication app Period for Reply | | | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any Status | | | | | | | | |
| 1) Responsive to communication(s) filed on | | | | | | | | |
| | is action is non-final. | | | | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | | | |
| Disposition of Claims | | | | | | | | |
| 4) Claim(s) 1-7 is/are pending in the application. | | | | | | | | |
| 4a) Of the above claim(s), is/are withdraw | wn from consideration. | • | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | | | |
| 6)⊠ Claim(s) <u>1-7</u> is/are rejected. | | | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | | | |
| 8) Claims are subject to restriction and/or | election requirement. | | | | | | | |
| Application Papers | | | | | | | | |
| 9) The specification is objected to by the Examine | er. | | | | | | | |
| 40.0 | o by the Examiner. | | | | | | | |
| 11) The proposed drawing correction filed on is: a) approved b) disapproved. | | | | | | | | |
| 12) The oath or declaration is objected to by the Ex | | oved. | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | | | |
| - | priority under 35 H.S.C. \$ 110(a) | /-/\ /5\ | | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: | | | | | | | | |
| 1. Certified copies of the priority documents | have been received | | | | | | | |
| _ | | | | | | | | |
| — | | | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | | |
| 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). | | | | | | | | |
| | | | | | | | | |
| Attachment(s) | | | | | | | | |
| 5) Notice of References Cited (PTO-892) 6) Notice of Draftsperson's Patent Drawing Review (PTO-948) 7) Information Disclosure Statement(s) (PTO-1449) Paper No(s) | (PTO-413) Paper No(s) Patent Application (PTO-152) | | | | | | | |

U.S. Patent and Trademark Office PTO-326 (Rev. 01-01) Application/Control Number: 09/535,951

Art Unit: 1617

DETAILED ACTION

Claim Objections

Claim 1 is objected to because of the following informalities: the term "non-steroidal", in line 5, is apparently misspelled as "non-steoidal". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,2, 5, and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "minimal effect" in claim 1, line 4 is a relative term which renders the claim indefinite. The phrase "minimal effect" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear what progestational agents are encompassed by the claim.

Further, the nature of "effects" on the sex organs encompassed by the claims is unclear. See, e.g., claim 2.

Claim 7 contains the trademark/trade name SCH-23390. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope

Art Unit: 1617

is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a non-steroidal benzazepine compound and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1,2, and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aristoff et al. (WO90/15816).

Aristoff et al. teaches a method of treating angiogenesis disorders, broadly, including atherosclerosis using angiostatic steroid compounds, broadly, including 17-hydroxyprogesterone (see particular page 3, line 22 and page7, line 30; claim 8).

Aristoff et al. does not expressly teach the use of 17-hydroxyprogesterone in a method to treat atherosclerosis specifically.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to use 17-hydroxyprogesterone in a method to treat atherosclerosis.

Application/Control Number: 09/535,951

Art Unit: 1617

One of ordinary skill in the art would have been motivated to use 17-hydroxyprogesterone in a method to treat atherosclerosis because any known angiostatic steroid compound including 17-hydroxyprogesterone, would have been reasonably expected to be useful in a method of treating an angiogensis disorder such as atherosclerosis, based on Aristoff et al.

Claims 1,3, 4, 6, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cincotta (US Patent 5,565,454).

Cincotta et al. teaches a method of in treating atherosclerosis using prolactin enhancer and/or prolactin inhibitors including haloperidol (see particular Col. 1, line 32 - Col.2, line 15; also Col.2, line 25 – 34; also Col.6, line 5-9).

Cincotta et al. does not expressly teach the use of haloperidol specifically in a method of treating atherosclerosis.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to use haloperidol in a method to treat atherosclerosis.

One of ordinary skill in the art would have been motivated to use haloperidol in a method to treat atherosclerosis because any known prolactin modulator compounds, including haloperidol, would have been reasonably expected to be useful in a method to treat atherosclerosis based on Cincotta et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming. Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Monday to Friday from 8:30 to 5:00.

Application/Control Number: 09/535,951

Art Unit: 1617

Page 5

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui June 15, 2001

MINNA MOEZIE, J.D.

SUPERVISORY PATENT EXAMINER

TECHNOLOGY CENTER 1600